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08/785,455	01/17/1997	JOHN E. HODGSON	P31353	4038

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/15/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/785,455

Applicant(s)

HODGSON ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26, 46, 47, 49-54 and 56-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46, 47, 50-52 and 56-58 is/are allowed.
- 6) ☒ Claim(s) 26, 49, 53, 54, 59-64 and 70-91 is/are rejected.
- 7) ☒ Claim(s) 65-69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Application Status***

1. The instant application has been previously suspended (Paper No. 21) due to a potential *ex parte* interference. This issue has been resolved and prosecution is being reopened herein. Claims 26, 46, 47, 49-54, and 56-91, previously noted as being allowed, are pending in the instant Office action and will be examined herein in full consideration of present Office policies and practices.

### ***Priority***

2. The instant application is granted the benefit of priority for the foreign applications 9601095.4 and 9615845.6 filed in the United Kingdom on January 19, 1996 and July 27, 1996, respectively, as requested in the declaration. The Examiner notes that the full-length methionyl tRNA synthetase sequence is disclosed in the latter foreign application; thus, the pending claims are afforded an earliest effective filing date of July 27, 1996.

### ***Information Disclosure Statement***

3. The information disclosure statement filed on February 2, 1998 has been previously considered as noted in Paper No. 9.

### ***Objections to the Specification***

4. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

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---Polynucleotides encoding Methionyl tRNA Synthetase from *Staphylococcus Aureus*,  
related products and methods---

5. The specification is objected to for not having a complete Abstract as required by M.P.E.P. § 608.01(b). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the full name of the enzyme, methionyl tRNA synthetase, and the source species, *Staphylococcus aureus*, for completeness.

6. The specification is objected to for having inconsistent citations. Throughout most of the specification, reference material is noted in parentheses immediately following the passage. However, on pages 30-31, superscripts are introduced with a reference section on page 31. Consistency in citation of references is required.

### ***Objections to the Claims***

7. Claim 65 is objected to as a duplicate claim of Claim 50 or 52 (see rejection under 35 U.S.C. § 112, second paragraph below). The scope of the claimed polynucleotide is identical, that is comprising (or consisting of) SEQ ID NO:1 from 1 to 1971.

8. Claims 65-69 are objected to for depending from a rejected claim.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 26, 49, 53, and 54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "about" is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Clarification is required.

10. Claims 65-74 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the transitional phrase "consists of", which closes the sequence of the polypeptide at only the claimed sequence with nothing added to the ends, is confusing; it seems the claims are intended only to indicate a particular item from Claim 60 and not unduly limit the subject matter. Amendment to more open language is suggested.

11. Claims 59 and 64 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is confusing how the complementary sequence, which is within the scope of Claim 56, can produce a methionyl tRNA synthetase in a host cell since it does not encode said protein. Clarification is required.

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The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 26, 49, 53, 54, 60-64, and 70-91 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The polynucleotides of the instant claims are not limited by a *specific* structure and function since the function lacks the specificity disclosed in the specification – SEQ ID NO:2 is a methionyl tRNA synthetase. Claims 26, 49, 53, 54, 60-64, and 70-74 are drawn to a genus of structures of any function. Claims 75-91 are drawn to a genus of structures having a generic function that does not require the entire molecule as disclosed.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical

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characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification teaches a polynucleotide (SEQ ID NO:1) encoding a methionyl tRNA synthetase (tRS) from *S. aureus* (SEQ ID NO:2). Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations (a limited number of mutations) and functional limitations (i.e., encoding a polypeptide having methionyl tRS activity). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of specific, functional limitations. The requirement of methionyl tRS is evident because the specification does not teach other tRSs of any sequence.

The Examiner suggests requiring the specific activity of encoding a polypeptide having methionyl tRNA synthetase for the claimed polynucleotide. Where polynucleotides encoding fragments of the disclosed polypeptide are desired, the Examiner suggests closed claim language.

13. Claims 26, 49, 53, 54, 60-64, and 70-91 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for SEQ ID NO:1 polynucleotides encoding polypeptides having methionyl tRNA synthetase activity, does not reasonably provide enablement for polynucleotides encoding polypeptides with related structure but unrelated functions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make a significant portion of all the embodiments encompassed by the claims would require undue experimentation.

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The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification teaches SEQ ID NO:2, a methionyl tRNA synthetase (tRS) protein from *S. aureus*, and SEQ ID NO:1, an *S. aureus* gene exactly encoding SEQ ID NO:2. The art includes few examples of methionyl tRS encoding genes. The art fully enables any DNA encoding SEQ ID NO:2 based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other methionyl tRS genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find



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a methionyl tRS gene, which is structurally related to SEQ ID NO:1, is not equivalent to the ability to make a methionyl tRS gene as required by the statute (i.e., “make and use”). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its methionyl tRS -nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

### ***Summary of Pending Issues***

14. The following is a summary of the issues pending in the instant application:

- a) The specification stands objected to because the title is not descriptive.
- b) The specification stands objected to for not having a complete Abstract.
- c) The specification stands objected to for having inconsistent citations.
- d) Claim 65 stands objected to as a duplicate claim of Claim 50 or 52.
- e) Claims 65-69 stand objected to for depending from a rejected claim.
- f) Claims 26, 49, 53, and 54 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the relative term "about".
- g) Claims 65-74 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the use of the transitional phrase “consists of”.
- h) Claims 59 and 64 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for methods of using the complementary sequence to make a protein.
- i) Claims 26, 49, 53, 54, 60-64, and 70-91 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- j) Claims 26, 49, 53, 54, 60-64, and 70-91 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

### ***Examiner's Comments***

15. The Examiner notes that SEQ ID NO:1 exactly encodes SEQ ID NO:2, starts with an “atg” and ends with a stop codon. The specification teaches methionyl tRNA synthetase activity of “purified MRS overexpressed in *E. coli*”; no direct mention of overexpression of SEQ ID

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NO:2 using a vector containing SEQ ID NO:1 in *E. coli* is found. However, SEQ ID NO:2 seems to be a full-length protein, and the Examiner has no reason to disagree with its assignment as a methionyl tRS.

***Conclusion***

16. Claims 46, 47, 50-52, and 56-58 are allowed. Claims 65-69 are objected to, and Claims 26, 49, 53, 54, 59-64, and 70-91 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **NON-FINAL** based on the new grounds of rejection presented in the instant Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK



October 13, 2003